

CLAIMS

- 1-37. (canceled)
38. (currently amended) A once-a-day composition comprising:
- (a) an immediate release component comprising bupropion or a pharmaceutically acceptable salt thereof wherein the immediate release component is a powder, a granule or an uncoated active pellet;
 - (b) a first pellet comprising a first core containing a pharmaceutically acceptable salt of bupropion and an enteric coating applied to the first core wherein the enteric coating consists of:
 - (i) a pH dependent coating polymer selected from the group consisting of shellac, methacrylic acid copolymers, cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, polyvinyl acetate phthalate and mixtures thereof;
 - (ii) a plasticizer; and
 - (iii) a lubricant;and wherein the first pellet releases bupropion in the upper gastrointestinal tract of a human patient; and
 - (c) a second pellet comprising a second core containing a pharmaceutically acceptable salt of bupropion and a sustained release coating applied to the second core wherein the sustained release coating comprises a mixture of:
 - (i) a water insoluble polymer;
 - (ii) a methyl acrylic acid copolymer;
 - (iii) a plasticizer; and
 - (iv) an antisticking agentand wherein the second pellet releases bupropion in the lower gastrointestinal tract of a human patient,
- wherein said composition is a tablet or capsule that contains 75 to 450 mg of bupropion or a pharmaceutically acceptable salt thereof, and the ratio of first pellet to second pellet is about 30:70 to about 70:30 and provides an in vivo plasma profile selected from:
- (a) a mean C_{max} of at least 50.0 ng/ml;
 - (b) a mean AUC_{0-inf} of greater than approximately 500.0 ng·hr/ml; and
 - (c) a mean T_{max} of between approximately 5.0 hours and 8.5 hours based upon a single dose administration of a composition containing 150 mg of bupropion or a pharmaceutically acceptable salt.
39. (previously presented) The composition of claim 38 wherein the immediate release component is an uncoated active pellet.
40. (cancelled) ~~The composition of claim 38 wherein said first pellet comprises a core containing the bupropion or pharmaceutically acceptable salt thereof and the pH dependent coating polymer is applied to the core.~~
41. (cancelled) ~~The composition of claim 38 wherein said second pellet comprises a core~~

~~containing the bupropion or pharmaceutically acceptable salt thereof and the water insoluble coating polymer is applied to the core.~~

42. ~~(cancelled) The composition of claim 38 wherein said pH dependent coating polymer is selected from the group consisting of shellac, methacrylic acid copolymers, cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, polyvinyl acetate phthalate and mixtures thereof.~~
43. (previously presented) The composition of claim 38 wherein said water insoluble coating polymer is selected from the group consisting of ethyl cellulose, cellulose acylate, cellulose diacylate, cellulose triacylate, cellulose acetate, cellulose diacetate, cellulose triacetate, cellulose acetate butyrate and mono-, di- and tri-cellulose arylates.
44. (previously presented) The composition of claim 38 wherein the composition is a tablet.
45. (previously presented) The composition of claim 38 wherein the composition is a capsule.
46. ~~(cancelled) The composition of claim 38 wherein the sustained release component further comprises a methacrylic acid copolymer.~~
47. (previously presented) The composition of claim 38 wherein the mean C_{\max} is less than 90 ng/ml.
48. (previously presented) The composition of claim 47 wherein the mean C_{\max} is less than 80 ng/ml.
49. (previously presented) The composition of claim 48 wherein the mean C_{\max} is less than 70 ng/ml.
50. (previously presented) The composition of claim 38 wherein the mean T_{\max} is 5.1 hours to 8.1 hours.
51. (currently amended) A once-a-day bupropion capsule consisting of:
 - (a) an immediate release component comprising a pharmaceutically acceptable salt of bupropion wherein the immediate release component is a powder, a granule or an uncoated active pellet;
 - (b) a first pellet comprising a first core containing a pharmaceutically acceptable salt of bupropion and an enteric coating applied to the first core wherein the enteric coating consists of:
 - (i) a pH dependent coating polymer selected from the group consisting of shellac, methacrylic acid copolymers, cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, polyvinyl acetate phthalate and mixtures thereof;
 - (ii) a plasticizer; and
 - (iii) a lubricant;and wherein the first pellet releases bupropion in the upper gastrointestinal tract of a

human patient; and

- (c) a second pellet comprising a second core containing a pharmaceutically acceptable salt of bupropion and a sustained release coating applied to the second core wherein the sustained release coating comprises a mixture of:

- (i) a water insoluble polymer;

- (ii) a methyl acrylic acid copolymer;

- (iii) a plasticizer; and

- (iv) an antisticking agent

and wherein the second pellet releases bupropion in the lower gastrointestinal tract of a human patient;

wherein said capsule contains 75 to 450 mg of bupropion, the ratio of first pellet to second pellet in the capsule is about 30:70 to about 70:30 and administration of the capsule to a patient provides an in vivo plasma profile selected from:

- (a) a mean C_{max} of at least 50.0 ng/ml;

- (b) a mean AUC_{0-inf} of greater than approximately 500.0 ng·hr/ml; and

- (c) a mean T_{max} of between approximately 5.0 hours and 8.5 hours based upon a single dose administration of a composition containing 150 mg of bupropion or a pharmaceutically acceptable salt.

52. (currently amended) A once-a-day bupropion tablet consisting of:

- (a) an immediate release component comprising a pharmaceutically acceptable salt of bupropion wherein the immediate release component is a powder, a granule or an uncoated active pellet;

- (b) a first pellet comprising a first core containing a pharmaceutically acceptable salt of bupropion and an enteric coating applied to the first core wherein the enteric coating consists of:

- (i) a pH dependent coating polymer selected from the group consisting of shellac, methacrylic acid copolymers, cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, polyvinyl acetate phthalate and mixtures thereof;

- (ii) a plasticizer; and

- (iii) a lubricant;

and wherein the first pellet releases the bupropion in the upper gastrointestinal tract of a human patient;

- (c) a second pellet comprising a second core containing a pharmaceutically acceptable salt of bupropion and a sustained release coating applied to the second core wherein the sustained release coating comprises a mixture of:

- (i) a water insoluble polymer;

- (ii) a methyl acrylic acid copolymer;

- (iii) a plasticizer; and

- (iv) an antisticking agent

and wherein the second pellet releases the bupropion in the lower gastrointestinal tract of a human patient; and

- (d) 25-40 weight percent of a solid pharmaceutically acceptable tablet excipient;

wherein said tablet contains 75 to 450 mg of bupropion, the ratio of first pellet to second pellet in the tablet is about 30:70 to about 70:30 and administration of the tablet to a

patient provides an in vivo plasma profile selected from:

- (a) a mean C_{\max} of at least 50.0 ng/ml;
- (b) a mean $AUC_{0-\infty}$ of greater than approximately 500.0 ng·hr/ml; and
- (c) a mean T_{\max} of between approximately 5.0 hours and 8.5 hours based upon a single dose administration of a composition containing 150 mg of bupropion or a pharmaceutically acceptable salt.

- 53. (previously presented) The composition of claim 38 wherein the first pellet releases the bupropion or pharmaceutically acceptable salt thereof at a pH corresponding to about 4.8 or lower and the second pellet releases the bupropion or pharmaceutically acceptable salt thereof at a pH corresponding to about 7 and above.
- 54. (previously presented) The composition of claim 51 wherein the first pellet releases the bupropion at a pH corresponding to about 4.8 or lower and the second pellet releases the bupropion at a pH corresponding to about 7 and above.
- 55. (previously presented) The composition of claim 52 wherein the first pellet releases the bupropion at a pH corresponding to about 4.8 or lower and the second pellet releases the bupropion at a pH corresponding to about 7 and above.